IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

PEDIAMED PHARMACEUTICALS, INC.	:	
v.	:	Civil Action No. DKC 2003-3443
BRECKENRIDGE PHARMACEUTICAL, INC., et al.	:	

MEMORANDUM OPINION

Presently pending and ready for resolution in this Lanham Act unfair competition case are: a motion by Plaintiff for partial summary judgment (paper 72); a motion by Defendants for summary judgment on all counts (paper 100); two motions by Plaintiff to seal exhibits (papers 73, 109); five motions by Defendants to seal exhibits (papers 79, 93, 99, 101, 112); a motion by Plaintiff for leave to supplement and to strike (paper 115); and a motion by Defendants for leave to file a surreply (paper 124). The issues are fully briefed and the court now rules pursuant to Local Rule 105.6, no hearing being deemed necessary. For the reasons that follow, the court will deny Plaintiff's motion for partial summary judgment; deny Defendants' motion for summary judgment; deny Plaintiff's and Defendants' motions to seal exhibits; deny as moot Plaintiff's motion to supplement and to strike; and deny as moot Defendants' motion to file a surreply. Finally, the court will require Plaintiff to show cause why Count 5 should not be dismissed because the count involves claims against individuals who are not parties to this suit.

I. Background

A. Factual Background

1. The Parties

The following facts are undisputed unless noted. Plaintiff, PediaMed Pharmaceuticals, Inc., whose principal place of business is Florence, Kentucky, is a pharmaceutical company that focuses on developing medicines for children. In 2001, Plaintiff contracted with Kiel Laboratories to manufacture Viravan-S ("Viravan").[1] Kiel produces Viravan using Tannate Conversion Technology ("TCT process"), a patented process that combines the active ingredients with tannic acid, which results in a prolonged release of the active ingredients and an improved ability to mask the taste. The process also results in fewer impurities in the finished product.[2] Designed for children, Viravan has a grape flavor that Plaintiff asserts gives the medicine a pleasing texture, smell, and flavor. One of Viravan's benefits is that it is administered only twice per day rather than four times per day. Plaintiff spends millions of dollars building awareness of Viravan. Plaintiff markets Viravan directly to doctors, and has distributed hundreds of thousands of samples to doctors.

---

[1] Kiel is not a party to this suit.

[2] One of Plaintiff's experts explained the benefits of the TCT process as: "a better impurity profile, utilization of standardized materials, USP grade materials, much greater reproducibility of the materials generated . . . [and] lack of organic solvents." (Paper 72, ex. 4, Thomas dep., 131).

Defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge"), whose principal place of business is Boca Raton, Florida, is a privately held pharmaceutical company specializing in marketing, research, and development. Breckenridge considers itself to be one of the "leading generic pharmaceutical drug companies in the United States." (Paper 72, ex. 8, Lapila dep. I, 43). At some point, Breckenridge decided to produce and market a generic version of Viravan, and in mid-2003, Breckenridge contracted with co-Defendant Scientific Laboratories, Inc. ("SLI"), whose principal place of business is Lanham, Maryland, to manufacture V-Tann.[3] Breckenridge began selling V-Tann in September 2003. V-Tann's advertising materials expressly identify Viravan as the comparable brand and state: "Compare the active ingredients in Viravan-S." (Paper 72, ex. 27). Breckenridge markets its products primarily to drug wholesalers, distributors, chain drugstores, and pharmacists.[4] Breckenridge and SLI (collectively, "Defendants") do not dispute Plaintiff's assertion that they market V-Tann by comparing it to Viravan.

[3] Larry Lapila, a Breckenridge vice president, was unsure whether Breckenridge or SLI first had the idea to create a generic version of Viravan.

[4] The parties have focused primarily on the substitution decisions of pharmacists. The court's discussion therefore will focus on pharmacists. Mr. Lapila testified that Defendants did not send their advertising materials to doctors. (Paper 72, ex. 8, Lapila dep. I, 67).

2. Viravan and V-Tann

Viravan and V-Tann have two active ingredients: phenylephrine tannate, a nasal decongestant, and pyrilamine tannate, an antihistamine. The labels on both products claim to have 12.5 mg of phenylephrine tannate and 30 mg of pyrilamine tannate per 5 milliliters. Plaintiff asserts that Viravan and V-Tann are different in several ways. First, V-Tann was formulated to contain 15% more of both phenylephrine tannate and pyrilamine tannate than Viravan. Lane J. Brunner, an expert for Plaintiff, stated that for this reason the two products are not pharmaceutically equivalent. Second, SLI manufactures V-Tann with a broader range of acceptable variation for the active ingredients than the specification range used by Kiel. Plaintiff asserts that Kiel uses a specification range of 90%-110%, while the specification range for V-Tann is 80%-120%. Lamar Furr, an expert for Plaintiff, stated that an 80%-120% deviation from the label "would be unacceptable" and "demonstrates a poorly controlled manufacturing process" (paper 72, ex. 5, Furr rep., 2), and Dr. Brunner stated that because the two products have different specification ranges, the two products are not pharmaceutically equivalent.

Third, Viravan is made with United States Pharmacopeia/National Formulary ("USP")-grade ingredients, while V-

Tann contains non-USP grade active ingredients.[5] Fourth, the TCT process used by Kiel is a different manufacturing process than the process used by SLI. Before launching V-Tann, SLI did not perform tests to determine whether V-Tann and Viravan are bioequivalent.[6]

3. Generic Equivalency and Substitution of Drugs

The substitution of a brand name drug with a generic drug is governed by state law. Certain states, including Maryland, mandate

---

[5] The evidence is not entirely clear whether all of Plaintiff's ingredients are USP grade. It appears that the key active ingredients – phenylephrine tannate and pyrilamine tannate – may not be USP grade. One of Plaintiff's witnesses, Greg H. Thomas, testified that "[t]he materials we utilize are USP recognized and standardized. The materials from other processes are not." (Paper 72, ex. 4, Thomas dep., 132). He then explained:

> The USP does not recognize tannate materials. There's no USP standards available for them. There are USP standards for phenylephrine hydrochloride, there are USP standards for pyrilamine maleate, there are USP standards for tannic acid, those are the materials we utilize in our product. Other companies don't utilize those materials, they're utilizing phenylephrine tannate, that is, nonstandard material. There's no standard in the world for phenylephrine tannate or pyrilamine tannate.

Id. at 132-33. Rajeshwari Patel, SLI's president, stated that "[e]verybody's using only nonstandard . . . Only in-house standard. Whenever you do assay, you use your own in-house standard, because USP is not available." (Paper 98, ex. 22, Patel dep., 117).

[6] One court gave the following explanation of bioequivalence: "'Bioequivalence' is a term used by the [Food and Drug Administration] to indicate that two drugs with the same active ingredient have essentially the same rate and extent of absorption into the bloodstream." *Pfizer, Inc. v. Miles, Inc.*, 868 F.Supp. 437, 441 n.1 (D.Conn. 1994).

the use of the *Approved Drug Products with Therapeutic Equivalence Evaluations*, also known as the "Orange Book," as the substitution standard.[7] According to the Orange Book, which is compiled by the Food and Drug Administration ("FDA"), two products are pharmaceutically equivalent if they:

> [C]ontain the same active ingredient(s), are of the same dosage form, route of administration and are identical in strength or concentration . . . Pharmaceutically equivalent drug products are formulated to contain the same amount of active ingredient in the same dosage form and to meet the same or compendial or other applicable standards (i.e. strength, quality, purity, and identity), but they may differ in characteristics such as shape, scoring configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration time, and, within certain limits, labeling.

---

[7] For instance, the relevant portion of Maryland law provides:

> (c) A pharmacist may substitute a generically equivalent drug . . . of the same dosage form and strength, for any brand name drug . . . if:
>
> (1) The authorized prescriber does not state expressly that the prescription is to be dispensed only as directed;
>
> (2) The substitution is recognized in the United States Food and Drug Administration's current list of approved drug or device products with therapeutic equivalence evaluations; and
>
> (3) the consumer is charged less for the substituted drug . . . Than the price of the brand name drug . . . .

MD. CODE ANN., HEALTH OCC. § 12-504.

Approved Drug Products with Therapeutic Equivalence Evaluations, vii (25th ed. 2005); *see also* 21 C.F.R. § 320.1(c) ("Pharmaceutical equivalents means drug products in identical dosage forms that contain identical amounts of the identical active drug ingredients . . . and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, whenever applicable, content uniformity, disintegration times, and/or dissolution rates."). Norman Campbell, one of Plaintiff's experts, declared that in states that use the Orange Book as the reference standard, a pharmacist may not legally substitute a drug if it is not listed in the Orange Book.

Other states require a determination by the pharmacist of bioequivalence or pharmaceutical equivalence, and if a drug fails to meet this standard, the drug may not be substituted.[8] Martin Manco, who appears to be a PediaMed executive, stated that drug manufacturers also attempt to influence the substitution decisions of pharmacists through direct advertising, such as faxes and e-mails, and through drug databases such as the First Data Bank and the Red Book.[9]

---

[8] The Orange Book states that drugs are therapeutic equivalents "only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling." *Approved Drug Products with Therapeutic Equivalence Evaluations,* at vi.

[9] The First Data Bank publishes what is referred to in the (continued...)

Neither Viravan nor V-Tann is listed in the Orange Book. From the papers, it appears that Viravan is not a "new drug," as defined by the FDCA.[10] If the original or brand name drug (i.e., Viravan) is not a "new drug," the drug that claims to be generic or equivalent (i.e. V-Tann) does not undergo the "abbreviated new drug application" ("ANDA"), which requires a manufacturer to demonstrate

---

[9](...continued)
industry as the "Blue Book." The Red Book is published by Medical Economics Co., Inc. These are independent publishing companies that compile information on drug pricing. *Montana v. Abbot Labs.*, 266 F.Supp.2d 250, 252-53 & n.2 (D.Mass. 2003). Mr. Manco referred to these reference sources as "advertising." (Paper 72, ex. 1, Manco dep., 128).

[10] The FDCA defines a new drug as:

> (1) Any drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or
>
> (2) Any drug . . . the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

21 U.S.C. § 321(p).

that the two drugs are therapeutically equivalent, pharmaceutically equivalent, and bioequivalent.[11] *See Solvay Pharms. v. Ethex Corp.*, No. 03-2836 JRTFLN, 2004 WL 742033, 2 (D.Minn. Mar. 30, 2004). Going through the new drug application and ANDA process leads to inclusion in the Orange Book. *Id*. Defendants' packaging insert states that "[a]ll prescription substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product." (Paper 72, ex. 26).

B. Procedural Background

Plaintiff's complaint, filed December 3, 2003, contains the following counts: (1) violation of Lanham Act § 43(a) for false advertising; (2) violation of Lanham Act § 43(A) unfair competition; (3) common law unfair competition; and (4) tortious interference with Plaintiff's business relationships with drug wholesalers, distributors, pharmacies, managed care organizations, pharmacists, physicians, pharmacy benefit managers, and similar medically related businesses and entities. In addition, in Count 5, Plaintiff requests a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202 that it is unlawful for pharmacists to substitute prescriptions written for Viravan with V-Tann.

Plaintiff has filed a motion for partial summary judgment on the Lanham Act claims. Plaintiff argues that it is entitled to

[11] One court referred to such drugs as "grandfathered." *Healthpoint Ltd. v. Ethex Corp.*, 273 F.Supp.2d 817, 841 (W.D.Tex. 2001).

summary judgment as a matter of law because Defendants' advertising materials are literally false and V-Tann is not equivalent to Viravan. Defendants oppose Plaintiff's motion for summary judgment, arguing: Plaintiff has come to court with unclean hands; V-Tann's label and advertising claims are true; Defendants' use of the "compare" statement is not literally false; a survey proffered by Plaintiff is not scientific, therefore the court should not consider it; and Plaintiff's claims are precluded by the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*.[12]

Defendants then cross moved for summary judgment on all counts. With respect to the Lanham Act counts, Defendants argue that Plaintiff's claims do not satisfy the Lanham Act because (1) Defendants' advertising is not literally false, nor does it have a tendency to deceive; and (2) Defendants' message is not material in that it is not likely to influence the decisions of pharmacists. Defendants also argue that the court should grant summary judgment in its favor on all counts because Plaintiff has unclean hands.

The parties have filed additional motions. Plaintiff has filed a motion for leave to supplement its response and to strike; Defendants have filed a motion for leave to file a surreply; and both Plaintiff and Defendants have filed motions to seal.

---

[12] The parties refer to this issue as "preemption." Pre-emption is based on the Supremacy Clause, Article VI, and involves the relationship between federal and state laws. Preclusion involves the relationship between two federal laws. *See CSX Transp., Inc. v. Miller*, 159 Md.App 123, 161-65 (2004).

The court will first address the preclusion issue, then Defendants' unclean hands argument as it relates to Plaintiff's allegedly false advertising, and finally the cross motions for summary judgment on the Lanham Act claims.

II. Standard of Review

It is well established that a motion for summary judgment will be granted only if there exists no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *See* Fed.R.Civ.P. 56(c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). In other words, if there clearly exist factual issues "that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party," then summary judgment is inappropriate. *Anderson*, 477 U.S. at 250; *see also Pulliam Inv. Co. v. Cameo Props.*, 810 F.2d 1282, 1286 (4th Cir. 1987); *Morrison v. Nissan Motor Co.*, 601 F.2d 139, 141 (4th Cir. 1987). The moving party bears the burden of showing that there is no genuine issue as to any material fact and that he or she is entitled to judgment as a matter of law. *See* Fed.R.Civ.P. 56(c); *Catawba Indian Tribe of S.C. v. South Carolina*, 978 F.2d 1334, 1339 (4th Cir. 1992), *cert. denied*, 507 U.S. 972 (1993).

When ruling on a motion for summary judgment, the court must construe the facts alleged in the light most favorable to the party opposing the motion. *See United States v. Diebold*, 369 U.S. 654,

655 (1962); *Gill v. Rollins Protective Servs. Co.*, 773 F.2d 592, 595 (4th Cir. 1985). A party who bears the burden of proof on a particular claim must factually support each element of his or her claim. "[A] complete failure of proof concerning an essential element . . . necessarily renders all other facts immaterial." *Celotex Corp.*, 477 U.S. at 323. Thus, on those issues on which the nonmoving party will have the burden of proof, it is his or her responsibility to confront the motion for summary judgment with an affidavit or other similar evidence in order to show the existence of a genuine issue for trial. *See Anderson*, 477 U.S. at 256; *Celotex Corp.*, 477 U.S. at 324. However, "[a] mere scintilla of evidence in support of the nonmovant's position will not defeat a motion for summary judgment." *Detrick v. Panalpina, Inc.*, 108 F.3d 529, 536 (4th Cir.), *cert. denied*, 522 U.S. 810 (1997). There must be "sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (citations omitted).

When faced with cross motions for summary judgment, as in this case, the court must consider "each motion separately on its own merits to determine whether either of the parties deserves judgment as a matter of law." *Rossignol v. Voorhaar*, 316 F.3d 516, 523 (4th Cir. 2003) (internal quotation marks omitted); *see also HavePower, LLC v. Gen. Electric Co.*, 256 F.Supp.2d 402, 406 (D.Md. 2003)

(citing 10A Charles A. Wright, *et al.*, *Federal Practice & Procedure* § 2720 (3rd ed. 1983)). The court reviews each motion under the familiar standard for summary judgment, *supra*. The court must deny both motions if it finds there is a genuine issue of material fact, "[b]ut if there is no genuine issue and one or the other party is entitled to prevail as a matter of law, the court will render judgment." 10A *Federal Practice & Procedure* § 2720.

III. Preclusion

Defendants argue that all of Plaintiff's claims are precluded because the claims involve enforcement and interpretation of the FDCA and the regulations promulgated thereunder. Defendants contend that Plaintiff's claims are an improper attempt to create a private cause of action for violations of the FDCA and that the FDA has sole and exclusive enforcement jurisdiction of the FDCA. (Paper 98, at 43). In responding to Defendants' unclean hands argument, Plaintiff makes the same contention: Defendants' argument is an improper attempt to enforce the FDCA, and only the FDA can make the determinations that underlie Defendants' unclean hands defense. (Paper 108, at 4).

The FDCA states that all proceedings for the enforcement of its provisions "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Those enforcement powers include the regulation of adulterated drugs, i.e., a drug whose "strength differs from, or its quality or purity falls below" the standards

set by the USP, *see* § 351, and the regulation of misbranded drugs, i.e., a drug that bears a false or misleading label, *see* § 352. A claim cannot stand if it comes "too close to the exclusive enforcement domain of the FDA." *Summit Tech., Inc. v. High-Line Med. Instruments Co.,* 922 F.Supp. 299, 306 (C.D.Cal. 1996). However, the FDA's administrative scheme should not be allowed to "eviscerate a Lanham Act or related common law claim over which the agency has no jurisdiction." *Healthpoint Ltd. v. Stratus Pharms., Inc.*, 273 F.Supp.2d 769, 792-93 (W.D.Tex. 2001).

In *Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993), the United States Court of Appeals for the Fourth Circuit recognized that the FDCA does not create a private cause of action. The plaintiff, Mylan Laboratories ("Mylan"), sued several manufacturers of generic drugs and several employees of the FDA, claiming essentially that the defendants had conspired to facilitate fraudulent FDA approval of their new drug applications, while wrongfully delaying the processing of Mylan's new drug applications. Mylan's claims included an allegation that the defendants violated the Lanham Act by making false and misleading representations about the defendant manufacturers' generic drugs. *Id*. at 1137. More specifically, Mylan alleged that the defendants' package inserts, brochures, and other advertisements falsely represented or implied that the defendants' drugs were

bioequivalent to Mylan's drugs, and were FDA approved. *Id*. at 1137-38.

On the defendants' motion to dismiss, the court found that Mylan had stated a proper claim regarding bioequivalence, and allowed that portion of the claim to proceed. *Mylan Labs.*, 7 F.3d at 1138. However, the court found that Mylan failed to state a Lanham Act claim for false advertising with respect to FDA approval. The court first noted that the defendants' statements and representations did not expressly declare "proper FDA approval." *Id*. at 39. The court also raised the issue of preclusion:

> Mylan . . . is not empowered to enforce independently the FDCA. *Cf. Sandoz* [*Pharm. Corp. v. Richardson-Vicks Inc.*], 902 F.2d [222] at 230 [(3rd Cir. 1990)] ("The Lanham Act is primarily intended to protect commercial interests . . . .[It] provides a private remedy to a commercial plaintiff who meets the burden of proving that its commercial interests have been harmed by a competitor's false advertising. The [FDCA], in contrast, is not focused on the truth or falsity of advertising claims" but on protecting the public interest in safety and efficacy (citations omitted)); *see also* FDCA, 21 U.S.C. § 337 (authorizing enforcement proceedings only by the United States and, under some circumstances, by a state).

Id.

Although *Mylan* provides some useful discourse on the preclusion issue, it is not entirely on point with the present case because *Mylan* involved drugs for which the FDA had made a

determination of equivalency, and thus the FDA's jurisdiction was clear.[13] This case involves a class of drugs that is not required to file a new drug application or an ANDA, and the FDA typically does not make a equivalency determination for these drugs. Other courts have considered preclusion challenges in claims involving non-Orange Book drugs (i.e. where the FDA does not determine equivalency), and have drawn a line between claims that involve application and interpretation of the FDCA and its implementing regulations, and claims that do not. *See Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F.Supp.2d 967, 975 (E.D.Wis. 2005) (allowing the plaintiff's complaint to proceed "to the extent that it is not seeking the interpretation or direct application of any FDA regulation"); *Solvay Pharms., Inc. v. Global Pharms.*, 298 F.Supp.2d 880, 884 (D.Minn. 2004) (allowing the plaintiff's claims to proceed and noting that "FDA approval is not required in order to substitute the products or to make a determination of bioequivalence or therapeutic equivalence"); *Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F.Supp.2d 1048, 1055 (E.D.Mo. 2002)(allowing the plaintiff's claims to proceed to the extent that

[13] In *Mylan*, the defendants' had filed an ANDA for their drugs, which leads to a generic determination by the FDA and inclusion in the Orange Book. In a footnote, the *Mylan* court stated that "[n]o generic drug may be marketed without FDA approval of an ANDA." *Mylan*, 7 F.3d at 1132 n.1. This is true if the original or brand name drug is a "new drug." However, as noted in Part IA3, if the original drug was not required to file a new drug application, the generic or equivalent drug does not file an ANDA.

the claims did not rely on the FDCA); *Stratus,* 273 F.Supp.2d at 793 (stating that "issues that require direct application or interpretation of the FDCA or its implementing regulations or FDA policies should not be addressed by the Court" but "other issues are able to be resolved without the direct application or interpretation of the FDCA, implementing regulations or FDA policies"); *Healthpoint, Ltd. v. Ethex Corp.*, 273 F.Supp.2d 817, 845 (W.D.Tex. 2001) ("There is a distinction between respecting the FDA's primary jurisdiction to determine in the first instance whether a drug is lawful, 'generic,' 'bioequivalent,' 'therapeutically equivalent,' or 'pharmaceutically equivalent' and, on the other hand, a Lanham Act claim that a false statement has been made about a product.").

When the advertising at issue directly or indirectly implied that one non-Orange Book drug was the generic of or equivalent to another drug, courts have split over whether a claim was precluded. *See First Horizon*, 228 F.Supp.2d at 1055 (stating that this issue "is better left to the FDA" because "this Court would be forced to determine FDA policy in order to determine the truth or falsity of the 'generic' nomenclature"); *Ethex*, 273 F.Supp.2d at 846 n.140 (finding the generic claim was within the FDA's jurisdiction); *Stratus*, 273 F.Supp.2d at 793 n.147 (same); *but see Schwarz*, 388 F.Supp.2d at 975 (allowing the plaintiff's claim to proceed where the defendant used the term "reference" in comparing its drug to

the plaintiff's drug); *Solvay*, 298 F.Supp.2d at 885 (allowing "generic" claims to proceed).

This court agrees with the analysis in *Schwarz* and *Solvay*, which found that express or implied claims of generic or pharmaceutical equivalence were not precluded where the drug was not listed in the Orange Book and there was no indication that FDA approval is needed to make a claim of equivalency. In *Schwarz*, the court reasoned:

> Schwarz's expert states in his report that neither the NULEV or NEOSOL products has been listed in the Orange Book and there is no record of the FDA evaluating the two products for pharmaceutical equivalence. In its brief, Breckenridge points out that the "FDA has not requested the submission of evidence regarding whether NULEV and NEOSOL are pharmaceutically equivalent, bioequivalent, therapeutically equivalent, or whether NEOSOL is in any respect a 'reference' to NEOSOL [sic], or whether NEOSOL is an 'equivalent' of NULEV." In the absence of any FDA ruling or ongoing investigation, there is little chance that the court will usurp the role of the FDA.

Schwarz, 388 F.Supp.2d at 975 (internal citations omitted). Similarly, the *Solvay* court observed:

> Solvay's claims are not related to FDA approval, or lack thereof. Solvay has raised claims based upon Defendants' allegedly false marketing assertions that the Lipram supplements are "generic," "comparable," "substitutable" or "equivalent" to Solvay's Creon line. Undisputably, neither Creon nor Lipram is listed in the FDA's Orange Book. FDA approval is not required in order to make a determination of bioequivalence or therapeutic equivalence. In addition, the FDA currently does not regulate the substitution

> of Lipram for Creon in any matter. Without any claims or factual assertions that tie Solvay's claims to FDA approval, Solvay has not attempted to privately enforce the provisions of the FDCA.

Solvay, 298 F.Supp.2d at 884-85.

In the present case, both Viravan and V-Tann appear to be in the class of drugs that is not required to file a new drug application or an ANDA and as a result, neither drug is listed in the Orange Book. There is no evidence that the FDA has made a determination as to whether V-Tann is a generic or therapeutic equivalent to Viravan, or that it is planning to do so. Defendants do not argue that the FDA typically makes an equivalency determination of the class of drugs not listed in the Orange Book. Moreover, Defendants have not pointed specifically to any portion of the FDCA or to any implementing regulations to support their assertion that Plaintiff's claims are based on the FDCA or its regulations, and therefore are precluded.

Defendants rely on *Healthpoint, Ltd. v. Stratus Pharmaceuticals, Inc*., 273 F.Supp.2d 769, 815-16 (W.D.Tex. 2001), in which a Texas court found that "the proper judicial approach is for the Court to defer to the FDA for the resolution of issues within its primary jurisdiction and to exercise jurisdiction over Lanham Act and other claims which do not require application or construction of FDA law, regulations or policy." Plaintiff correctly responds that the *Stratus* decision supports its position

because the court allowed claims involving comparative advertising to proceed to the extent that such claims did not invade the FDA's province. *See Stratus*, 273 F.Supp.2d at 793 ("[I]f Stratus represents that its two ointments are 'bioequivalent,' 'generically equivalent,' 'equivalent' or have 'the same active ingredients' or 'the same ingredients' or 'the same active ingredients in the same amounts,' consumer and competitors have a right to expect that such representations have factual support and the Lanham Act provides a vehicle to enforce that expectation." (footnote omitted)). Plaintiff's complaint contends that Defendants have improperly compared V-Tann to Viravan. These allegations are the type of comparative advertising claims that previous courts, including the *Stratus* court, have allowed to proceed.[14]

On the other hand, Defendants' cross motion for summary judgment is based, in part, on the argument that Plaintiff has unclean hands because Plaintiff illegally marketed Viravan. Defendants argue that Kiel manufactured adulterated drugs, and

[14] In its motion for summary judgment, Plaintiff alleges for the first time that Defendants' V-Tann label is literally false because it contains an overage of phenylephrine tannate and pyrilamine tannate. The FDCA has enforcement power over false and misleading labels. 21 U.S.C. § 352. To the extent that Plaintiff relies solely on the false label argument to find a Lanham Act violation, (paper 72, at 18)("[T]hese false statements regarding the amount of active ingredients were misrepresentations regarding the nature, characteristics or qualities of V-Tann. Consequently, Defendants' false representations were violations of the Lanham Act and PediaMed is entitled to summary judgment"), such a claim is essentially a mislabeling claim, which is within the jurisdiction of the FDA and thus would be precluded.

"Pediamed furthered the illegal act of introducing and delivering for sale an adulterated drug in violation of 21 U.S.C. § 331(a),(k)." (Paper 100, at 36). Defendants also assert that Viravan is mislabeled because they can show instances where the active ingredients for batches of Viravan fell below 100% of the amount stated on the label, in violation of the FDCA. (Paper 100, at 41). Finally, Defendants assert that Plaintiff failed to file a new drug application before selling Viravan.[15] (Paper 100, at 43).

These arguments (adulteration, mislabeling, and new drug applications) implicate various provisions of the FDCA. Because Defendants' argument requires direct application of the FDCA, which only the FDA is entitled to enforce, these arguments are precluded.[16] *See Stratus*, 273 F.Supp.2d at 798-99 (finding that the defendant's unclean hands argument that the plaintiff illegally marketed its drug without prior FDA approval is within the FDA's jurisdiction); *Inmuno Vital, Inc. v. Golden Sun, Inc.*, 49 F.Supp.2d 1344, 1359 (S.D.Fla. 1997) (stating that the defendant's unclean

[15] The FDCA regulates the procedure for approving new drugs. *See* 21 U.S.C. § 355.

[16] Because the court rejects this portion of Defendants' unclean hands argument, Plaintiff's motion to strike a press release and an FDA inspection report, and its request for judicial estoppel (paper 115) are moot. Furthermore, Defendants' motion to file a surreply to address this evidence (paper 120) will be denied as moot.

hands argument failed as a matter of law because the argument relied on alleged violations of the FDCA).

IV. Defendants' Remaining Unclean Hands Argument

In their cross motion for summary judgment, Defendants argue that Plaintiff has unclean hands because Plaintiff has falsely advertised Viravan, thereby violating the Lanham Act. (Paper 100, at 42). Defendants assert that Plaintiff's advertising is misleading, in violation of the Federal Trade Commission Act, 15 U.S.C. §§ 52 and 55, because (1) although the advertising suggests that children prefer Viravan, Plaintiff has never conducted testing to support this claim, and (2) Plaintiff uses fictitious testimonials. (Paper 100, at 41). Defendants cannot invoke the unclean hands defense because they cannot show they were harmed by Plaintiff's acts.

The Supreme Court has long recognized "the equitable maxim that he who comes into equity must come with clean hands." *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 815 (1945) (internal quotation marks omitted). The doctrine "closes the doors of a court of equity to one tainted with inequitableness or bad faith relative to the matter in which he seeks relief, however improper may have been the behavior of the defendant." *Id*. Although the doctrine "does not demand that its suitors shall have led blameless lives . . . it does require that

they shall have acted fairly and without fraud or deceit as to the controversy in issue." *Id*. at 814-15 (internal citations omitted).

An unclean hands defense requires that Defendants show they were injured by Plaintiff's conduct. *See Lawler v. Gilliam*, 569 F.2d 1283, 1294 (4th Cir. 1978) ("This defense . . . requires the defendant to show that he himself has been injured by the plaintiff's conduct."); *JTH Tax, Inc. v. H & R Block E. Tax Servs., Inc.,* 128 F.Supp.2d 926, 949 (E.D.Va. 2001) (stating that the elements of an unclean hands defense require defendant to demonstrate that "plaintiff's conduct injured the defendant"), *vacated in part on other grounds*, 28 Fed.Appx. 207 (4th Cir. 2002). Relying on cases from other circuits, Defendants argue that "[c]ausation and harm are presumed in a Lanham Act case where the plaintiff is an obvious competitor with respect to the misrepresented product." (Paper 111, at 9). First, Defendants misstate the rule about causation and harm in Lanham Act cases in the Fourth Circuit.[17] Second, Defendants' argument pertains to the burden of establishing a Lanham Act claim and not to a defendant's use of an unclean hands defense. The Fourth Circuit has made clear

[17] In *Scotts Co. v. United Indus. Corp.*, 315 F.3d 264, 272 (4th Cir. 2002), the Fourth Circuit recognized that a presumption of irreparable injury may be applied in trademark infringement cases, but did not reach the issue in a false advertising context because the plaintiff had failed to make a *prima facie* showing of consumer confusion. *See Scotts*, 315 F.3d at 273-74 ("We need not, however, decide whether and under what circumstances a presumption of irreparable harm should be applied in false advertising cases.").

that in order to use the unclean hands defense, Defendants must show they were injured by Plaintiff's conduct. Defendants have failed to do so. Accordingly, the court will deny Defendants' motion for summary judgment based on Plaintiff's alleged unclean hands (i.e. Plaintiff's alleged false advertisement of Viravan).

V. Cross Motions for Summary Judgment on the Lanham Act Claims

The Lanham Act prohibits a "false or misleading description of fact, or false or misleading representations of fact" that "misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). A plaintiff who asserts a claim under the Lanham Act must establish:

> (1) the defendant made a false or misleading description of fact or representation of fact in a commercial advertisement about his own or another's product; (2) the misrepresentation is material, in that it is likely to influence the purchasing decision; (3) the misrepresentation actually deceives or has the tendency to deceive a substantial segment of its audience; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products.

Scotts Co. v. United Indus. Corp., 315 F.3d 264, 272 (4th Cir. 2002).

A. False or Misleading Description of Fact

For Defendants to be liable, "the contested statement or representation must be either false on its face or, although literally true, likely to mislead and to confuse consumers given the merchandising context." *Scotts*, 315 F.3d at 273 (quoting *C.B. Fleet Co. v. SmithKline Beecham Consumer Healthcare, L.P.*, 131 F.3d 430, 434 (4th Cir. 1997)). If the advertisement is literally false, "a violation may be established without evidence of consumer deception." *Scotts*, 315 F.3d. at 273 (quoting *Cashmere & Camel Hair Mfrs. Inst. v. Saks Fifth Ave.*, 284 F.3d 302, 310 (1st Cir. 2002)). However, if the "plaintiff's theory of recovery is premised upon a claim of implied falsehood, a plaintiff must demonstrate, by extrinsic evidence, that the challenged [advertisements] tend to mislead or confuse consumers." Scotts, 315 F.3d. at 273 (quoting *Johnson & Johnson * Merck Consumer Pharms. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297 (2nd Cir. 1992) (internal quotation marks omitted)). Plaintiff's and Defendants' papers focus primarily on whether Defendants' "compare" statement is literally false.[18]

1. Literal Falsity

In analyzing whether an advertisement is literally false:

> "[A] court must determine, first, the unambiguous claims made by the advertisement . . . , and second, whether those claims are

[18] Plaintiff does not argue that Defendants' "compare" statement is literally true but likely to mislead and confuse consumers.

> false." *Novartis* [*Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*], 290 F.3d [578,] at 586 [(3rd Cir. 2002)]. "A literally false message may be either explicit or conveyed by necessary implication when, considering the advertisement in its entirety, the audience would recognize the claim as readily as if it had been explicitly stated." *Id.* at 586-87 (internal quotation marks omitted).

Scotts, 315 F.3d at 274. A claim of literal falsity must fail where the statement can reasonably be understood to convey different messages. *See Scotts*, 315 F.3d at 275-76.

Plaintiff asserts that the unambiguous claim Defendants have made in their "compare" statement is that Viravan and V-Tann are equivalent and that pharmacists may substitute Viravan for V-Tann.[19] (Paper 72, at 6). Mr. Lapila, a vice president for Breckenridge, agreed that the "compare" statement is intended to inform potential customers "that V-Tann is the generic equivalent to Viravan-S in that it has the same active ingredients, strength, dosage form, and route of administration," (paper 72, ex. 8, Lapila dep. I, 140), and that Defendants targeted pharmacists and others in a position to make drug substitution decisions. In addition, Plaintiff relies

---

[19] The relevant audience is pharmacists, drug wholesalers, distributors and chain drugstores, to whom Defendants sent their advertising materials. *See Cashmere & Camel Hair Mfrs.,* 284 F.3d at 312 n.11 ("The relevant 'consumers' are those groups of people to whom the advertisement was addressed."). *See also Stratus,* 273 F.Supp.2d at 812 (identifying pharmacists as the audience); *Mylan Labs. Inc. v. Pharm. Basics*, *Inc.*, 808 F.Supp. 446, 459 (D.Md. 1991) (distinguishing between advertisements targeted at the public and those targeted at pharmacists) *rev'd on other grounds*, 7 F.3d 1130 (4th Cir. 1993).

on a report by Brian Reisetter, whose survey ("Reisetter survey") of 150 pharmacists found that when pharmacists reviewed Breckenridge's specification sheet, which uses the phrase "compare the active ingredients" to Viravan, 51.3% believed the products to be pharmaceutically equivalent.[20] (Paper 72, ex. 16, Reisetter survey, ¶ 24).

Plaintiff argues the two drugs are not equivalent, and therefore the "compare" statement is literally false, because V-Tann is formulated to contain 15% more phenylephrine tannate and pyrilamine tannate than Viravan; Kiel uses a 90%-110% specification range while SLI uses a specification range of 80%-120%; Viravan is

---

[20] Defendants argue that the survey evidence is barred pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and the Federal Rules of Evidence 403, 702, and 703. The court has reviewed Dr. Reisetter's survey and Defendants' arguments against admissibility, and finds that the survey is sufficiently relevant and reliable to warrant consideration. *See, e.g., Indianapolis Colts, Inc. v. Metro. Balt. Football Club Ltd. P'Ship*, 34 F.3d 410, 416 (7th Cir. 1994) (holding that it was not clearly erroneous for the district court to consider survey evidence even though the survey was imperfect); *Mobil Oil Corp. v. Pegasus Petroleum Corp.*, 818 F.2d 254, 259 (2nd Cir. 1987) ("The district court properly admitted these surveys into evidence, despite claims of statistical imperfections by both sides, as those criticisms affected the weight accorded to the evidence rather than its admissibility."); *Jellibeans, Inc. v. Skating Clubs of Ga., Inc.*, 716 F.2d 833, 844 (11th Cir. 1983) ("These alleged technical deficiencies affect the survey's weight, however, and not its admissibility."). *See also* J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition,* § 32:170, at 32-276 (4th ed. 2005) ("[T]he majority rule is that while technical deficiencies can reduce a survey's weight, they will not prevent the survey from being admitted into evidence."). In light of the foregoing, Plaintiff's motion for leave to supplement its reply brief with additional arguments regarding the survey's admissibility is moot and will be denied.

manufactured using the TCT process while V-Tann is not; and Viravan contains non-USP active ingredients. (Paper 72, at 18-23). Plaintiff's experts have opined that V-Tann is not pharmaceutically equivalent to Viravan because of the different amounts of active ingredients and the different specification ranges.[21] (Paper 23, ex. 23, at 3).

Defendants assert that their advertising claims are true because V-Tann meets its label claims.[22] Defendants concede that V-Tann's manufacturing process calls for 15% more phenylephrine tannate and pyrilamine tannate than the amount stated on the label. Ms. Patel explained that adding more phenylephrine tannate and pyrilamine tannate enables V-Tann's final product to meet its label claims while allowing for decreases caused by the manufacturing process and degradation over time. In SLI's testing, the actual amount of the active ingredients in the finished product ranged from 109.7% to 113.92%. (Paper 98, ex. 11). In other words, Defendants argue that V-Tann's advertising is true because V-Tann "contains the same amount of active ingredients as Viravan purports to contain." (Paper 111, at 12).

---

[21] None of Plaintiff's expert witnesses have commented on whether the TCT process and the use of USP ingredients make Viravan different from V-Tann.

[22] Defendants also argue that "Pediamed claims that the term 'Compare the Active Ingredients' means 'FDA approved Orange Book therapeutic equivalent.'" (Paper 98, at 29). Defendants' statement mischaracterizes Plaintiff's claim. Plaintiff has never alleged that the "compare" statement means Orange Book approved.

Regarding the product specification range, Defendants assert that Plaintiff is applying the wrong standard for determining whether V-Tann meets its label claims (and therefore is comparable). Robert Falconer, an expert for Defendants, stated that because phenylephrine tannate and pyrilamine tannate are not in the USP, two other sources – the FDCA and current Good Manufacturing Practices ("cGMP"), 21 C.F.R. § 211.101(a) – provide "authoritative guidance," and these sources require a drug to have at least 100% of its stated active ingredients. (Paper 98, ex. 10, Falconer decl., ¶ 4). The FDCA provides that for a drug not listed in an official compendium such as the USP, the drug is adulterated when "its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess." § 351(c). The cGMP provides that "[t]he batch shall be formulated with the intent to provide not less than 100 percent of the labeled or established amount of active ingredient." 21 C.F.R. § 211.101(a). Mr. Falconer stated that for a non-USP drug, "only the manufacturer can determine an appropriate range of specification, because only the experience of the manufacturer can determine what is expected to occur as variation before, during or after the manufacturing process or finished product testing process." (Paper 98, ex. 10, Falconer decl., ¶ 10). Ms. Patel asserted: "We believe our range is within industry standards for the type of drug, type of active ingredient, manufacturing process utilized and based on

prior manufacturing experience." (Paper 98, ex. 3, Patel decl., ¶ 3).

Defendants also contend that the specification range for V-Tann is closer to 100%-110% (i.e. within Viravan's range) because even though some testing showed 113% of the active ingredients, the testing has an error rate of plus or minus four percent. Thus, a result of 113% is considered to be acceptable. (Paper 98, at 26). Defendants further assert that Kiel's TCT process is immaterial as an indicator of quality or how the finished product works, and that Plaintiff does not have any tests to show that the TCT process is unique or distinguishable from standard manufacturing processes. *Id.* at 27.

Finally, Defendants argue that their "compare" statement is not literally false because it can be reasonably understood to convey different messages, and only an unambiguous statement can be literally false. (Paper 98, at 29). Defendants point out that Plaintiff's expert, Dr. Reisetter, stated that the words "compare to" are "open to interpretation" in the pharmaceutical industry. (Paper 72, ex. 12, ¶ 37). Defendants also cite to *Zoller Labs., LLC v. NBTY, Inc*., 111 Fed.Appx. 978 (10th Cir. 2004) (affirming a district court's finding that there was more than one reasonable interpretation of the statement "compare to the ingredients"). *Zoller* is distinguishable, however, because it involved advertising claims made to the general public, not claims made to pharmacists,

who may understand the word "compare" as having certain specific connotations.

Having reviewed all the papers and evidence provided by Plaintiff and Defendants, the court concludes that there is a question of material fact as to whether Defendants' claims are literally false. On the one hand, Plaintiff provides expert witness statements that the products are not equivalent due to the 15% overage in the active ingredients and the differing specification range. On the other hand, Defendants assert that the overage is needed to ensure that V-Tann meets its label claims; the "compare" statement is not literally false because V-Tann meets its label claims; and only the manufacturer can determine the proper specification range for its product. Both Plaintiff and Defendants have presented evidence that some deviation from the amount stated on the label is acceptable, although the parties dispute what is the acceptable amount of deviation, how to calculate it, and whether the end result allows Defendants to claim that V-Tann is equivalent and therefore substitutable. Accordingly, there is a factual dispute over whether Defendants made a literally false statement, and neither party is entitled to summary judgment.[23]

[23] It is not necessary to discuss the other elements of a Lanham Act claim.

VI. Plaintiff's and Defendants' Motions to Seal

Plaintiff and Defendants have filed seven motions under Local Rule 105.11 to seal exhibits. (Papers 73, 79, 93, 99, 101, 109, 112). There is a well-established common law right to inspect and copy judicial records and documents. *See Nixon v. Warner Commc'ns Inc.*, 435 U.S. 589, 597 (1978). If the public's right of access is outweighed by competing interests, however, the trial court may, in its discretion, seal those documents from the public's view. *See In re Knight Publ'g Co.*, 743 F.2d 231, 235 (4th Cir. 1984). Local Rule 105.11 provides:

> Any motion seeking the sealing of pleadings, motions, exhibits or other papers to be filed in the Court record shall include (a) proposed reasons supported by specific factual representations to justify the sealing and (b) an explanation why alternatives to sealing would not provide sufficient protections. The Court will not rule upon the motion until at least 14 days after it is entered on the public docket to permit the filing of objections by interested parties. Materials that are the subject of the motion shall remain temporarily sealed pending a ruling by the Court. If the motion is denied, the party making the filing will be given an opportunity to withdraw the materials.

The documents that the parties seek to seal involve depositions, expert reports, test results, advertising materials, and batch records. The motions are unopposed.[24] The parties'

[24] Plaintiff originally sought to seal the reports of Norman Campbell (paper 72, ex. 11) and Brian Reisetter (paper 72, ex. 12). (Paper 73). Defendants opposed the motion, stating that they had agreed that these reports would not be sealed. (Paper 74). (continued...)

motions to seal do not offer either a proposed reason supported by specific factual representations to justify the sealing or an explanation as to why alternatives to sealing would not provide sufficient protections. The court will deny the motions because they do not comply with Rule 105.11. Plaintiff and Defendants will have 15 days to renew their motions with memoranda that comply with Rule 105.11. In the meantime, the papers will remain temporarily under seal. If Plaintiff and Defendants do not renew their motions, the papers will be unsealed.

VII. Plaintiff's Request for a Declaratory Judgment

Plaintiff's complaint seeks a declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Plaintiff seeks the following declarations: "[B]ecause V-Tann is not listed as a therapeutic equivalent to Viravan in the Orange Book, it is unlawful for pharmacists to substitute V-Tann for prescriptions of Viravan in Maryland and other Orange Book states;" "because V-Tann has not been proven to be therapeutically equivalent to Viravan, it is unlawful for pharmacists to substitute V-Tann for prescriptions of Viravan in Therapeutic Equivalence and Orange Book states;" and "because V-Tann is not pharmaceutically equivalent to Viravan, it is unlawful for pharmacists to substitute

[24](...continued)
Plaintiff has indicated that it no longer wishes to seal these reports. (Paper 75). Accordingly, the court need not consider this request, and the documents will not be sealed.

V-Tann for prescriptions of Viravan in Pharmaceutical Equivalence, Therapeutic Equivalence, or Orange Book states." (Paper 1, at 17-18). Plaintiff seeks a declaration that it is unlawful for pharmacist to substitute V-Tann for Viravan, however Plaintiff has not named pharmacists as parties to this lawsuit. *See Schwarz*, 388 F.Supp.2d at 975 (dismissing Plaintiff's request for declaratory relief involving pharmacists because "this court cannot make such declaration against entities who are not parties to this suit"); *Solvay*, 298 F.Supp.2d at 887 (dismissing Plaintiff's request for declaratory relief involving pharmacists because "[t]he Court does not have subject matter jurisdiction to make such a declaration against entities that are not party to this suit"). Accordingly, the court will require Plaintiff to show cause within 15 days of the date of this Order why Count 5 should not be dismissed.

VIII. Conclusion

For the foregoing reasons, the court will deny Plaintiff's motion for partial summary judgment; deny Defendants' motion for summary judgment; deny Plaintiff and Defendants' motions to seal exhibits; deny as moot Plaintiff's motion to supplement and to strike; deny as moot Defendants' motion to file a surreply; and require Plaintiff to show cause why Count 5 should not be dismissed. A separate Order will follow.

/s/
DEBORAH K. CHASANOW
United States District Judge